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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/582,869
Filing Date: June 14, 2006
Appellant(s): HANSEN, BERND

Mark S. Bicks
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 13, 2009 appealing from the Office action mailed August 13, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brieis correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

US 2004/00665983 A1	Hensen et al.	4-2004
US 2002/0159915 A1	Zelina et al.	10-2002
60049919	Furui Koichi	3-1985

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14, the phrase "a specified over-pressure" is vague and indefinite, because it is unclear what is the term "a specified over-pressure" comprised? - It is unclear at what pressure is "a specified over-pressure" being referred to?

3. Examiner's note: reference US 2004/0065983 A1 is being use as an English translation for the (DE 10063282 C2).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 12-14 and 17-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Hansen et al. (DE 10063282 C2).

Hansen et al. discloses an apparatus (as in claim 24) and a method (as in claim 12) comprising: at least one tube (3) of softened plastic material is extruded into an opened mold (6), the tube is closed at its projecting end when the mold (6) is closed to form the bottom of the container, the tube is separated above the mold by means of a separating element (21) to form a filler opening (15), and the mold is moved with the tube having the filler opening into a filling position in which the container, after it has been formed by generation in the mold of a pressure gradient acting on the tube and expanding it, is filled and then sealed (figures 1-2), the filler opening of the tube being covered by a sterile barrier (23) at least from the time of its formation to that of filling of the respective container, wherein by means of the sterile barrier (23) at least one sterile medium (it is construed that the heated plate heats the surrounding air, and the hot air is the sterile medium) is moved in the direction of the filler opening (15) by means of a media delivery device (23).

Hansen et al. further discloses:

Regarding claims 13 and 14, wherein the sterile medium is air; and the sterile medium is conveyed at a specified pressure in the direction of the filler opening (it is construed that the medium being conveyed to cover the filler opening, therefore it is under a specified pressure, because without pressure different, there would not be any movement of the medium).

Regarding claims 17 and 25, the sterile barrier is configured as a plate-shaped cover element (23) which, after separation of the tube, covers the filler opening and provides it with a sterile medium until filling of the container is undertaken after its expansion below the sterile filling space (as mention above, it is construed that heated air is the sterile medium).

Regarding claim 18, the cover element (23) moves together with the separating element (21) for separation of the plastic tube.

Regarding claim 19, the cover element moves synchronously with parts of the mold, and does not clear the filler opening until filling of the container (US 2004/0065983 - [0022], lines 1-8)

Regarding claims 20 and 21, wherein the container is rinsed by or partly filled with the respective medium by means of the media delivery device (23), by way of the filler opening (as mention above, it is construed that heated air is the sterile medium).

Regarding claims 22 and 23, wherein the sterile barrier and/or the sterile medium are heatable, by preference to a temperature higher than 120 degrees C, by preference to a temperature situated within the range of 150 to 200 degrees C (see claim 4).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 15, 16 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen et al. (DE 10063282 C2) in view of Zelina et al. (US 2002/0159915 A1).

As discussed above, Hansen et al. discloses the claimed invention, but it does not expressly disclose that a suction device in the form of a vacuum device.

Zelina et al. discloses an apparatus and a method in which the sterile medium is hydrogen peroxide ([0035] page 2) and a suction device in the form of a vacuum device (112) is used (figure 1) to provide means to sterilize and decontamination the sterile filling space (abstract).

Therefore, it would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified Hansen et al. by incorporating the use of sterile medium and vacuum device as taught by Zelina et al. to provide means for sterilizing and decontamination the sterile filling space to achieve the condition as recited in claims 15, 16 and 26.

8. Claims 12-14 and 17, 20 and 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Furui Koichi (JP 60049919 A).

Furui Koichi discloses (Figs. 1-3) an apparatus and a method comprising: at least one tube (6) of softened plastic material is extruded into an opened mold (8), the tube is closed at its projecting end when the mold is closed to form the bottom of the container, the tube is separated above the mold by means of a separating element to form a filler opening (not number), and the mold is moved with the tube having the filler opening into a filling position (Fig. 3) in which the container, after it has been formed by generation in the mold of a pressure gradient acting on the tube and expanding it, is filled and then

sealed (Figs. 3a-c), the filler opening of the tube being covered by a sterile barrier (12) at least from the time of its formation to that of filling of the respective container, wherein by means of the sterile barrier at least one sterile medium (aseptic pressure air - abstract) is moved in the direction of the filler opening by means of a media delivery device (abstract in English).

Regarding claims 13 and 14, wherein the sterile medium is air; and the sterile medium is conveyed at a specified pressure in the direction of the filler opening (Figs. 3a-c).

Regarding claims 17 and 25, the sterile barrier is configured as a plate-shaped cover element (it is construed that device 12 comprises plates that formed the device) which, after separation of the tube, covers the filler opening and provides it with a sterile medium until filling of the container is undertaken after its expansion below the sterile filling space.

Regarding claim 20, the container (14) is flushed across the filler opening by the sterile medium by the media delivery device.

Regarding claims 22 an 23, it is construed that since Furui Koichi discloses that the medium is aseptic pressure air, it anticipated the temperature requirement (as recited in claim 22 and 23) so that the air is qualified as aseptic air.

(10) Response to Argument

1. In response to the Appellant's argument (regarding the 112, second paragraph) that the terminology ("over pressure") is used in other U.S. patents, and such terminology is acceptable, the examiner agrees that the term "over-pressure" is

acceptable, but it should be pointed out that what renders claim 14 indefinite is the term "a specified", because it is unclear what is the limitation of the term “a specified”?

2. In response to the Appellant’s argument that:

> *“To the extent that heated air may be generated by the heated plate 23, such heated air, being of lighter weight than the surrounding ambient air, will move upwardly in a direction away from the fill openings in a manner similar to hot air in a balloon. Any heated air surrounding the Hansen German patent plate 23 will not move downwardly in the direction of the fill openings 15 in the tubes to provide a sterilization effect on the openings of the tubes or containers. In contrast, both the method of claim 12 and the device of claim 24 require conveying a sterile medium in a direction of the filler opening from the sterile barrier by the media delivery device or the media deliverer. Such method step and such structure are not disclosed or rendered obvious by the German Hansen patent, when considered alone or in combination with any of the other cited patent documents.”* (emphasis added),

this is not found persuasive for the following reasons:

Firstly, the argument that the heated air does not provide a sterilization effect on the opening of the tubes opening is mere speculation, because it is not supported by the disclosure. On the contrary, Hansen et al. (US 2004/0065983 A1) clearly discloses the following:

> *“The sterile barrier is in the form of a heatable plate movable together with the separating element severing the tube, the plate being heated to a germ-killing temperature, preferably above 150° C. In that the plate moves with the cutting edge severing the tube, the fill opening is covered by the heated plate even as the tube is being formed, that is, at no time is the fill opening uncovered."* ([0007]) (emphasis added).

Secondly, it is construed that as the heated plate or sterile barrier (23) being heated to the “germ-killing” temperature, the air surrounding of the heated plate also being heated, and because the heat source is on going (continuously), the surrounding air also being heated continuously (basic law of physics). As one clearly sees that, as

the result, the heated air of the surrounding of the heated plate is expanding continuously, propagating to continuously replacing the surrounding cool air and cover the area surrounding the mold, and thus protecting (sterilizing) the fill opening (15).

Finally, Hansen et al. (US 2004/0065983 A1) clearly discloses that the sterile medium is being conveyed to cover the filler opening:

> *"A cost-effective process with short cycle times is obtained if the heatable plate with the cutting edge for severance of the tube mounted on its leading edge is moved from a retracted initial position to an operating position is a direction in which the plate is mounted above the path of movement of the mould leading into the filling position, in such a way that the fill opening is covered by the plate throughout its travel to the filling position, and so that plate and cutting edge are then moved back from the operating position to the initial position after the mould has reached the filling position."* ([0009]) (emphasis added).

3. In response to the Appellant's argument regarding claims 13, 14, the examiner maintains that Hansen et al. discloses that "*the plate being heated to a germ-killing temperature, preferably above 150° C"* ([0007]) and thus the sterile medium is air as mentioned in the examiner response to the Appellant's argument above, and it is construed that the medium being conveyed to cover the filler opening, therefore it is under a specified pressure, because without pressure different, there would not be any movement of the medium – in other words, heated air is under a specified pressure higher than unheated air.

In response to the Appellant's argument regarding claims 17 and 25, the examiner maintains that the sterile barrier is configured as a plate-shaped cover element (it is construed that device 12 comprises plates that formed the device) which, after separation of the tube, covers the filler opening and provides it with a sterile

medium until filling of the container is undertaken after its expansion below the sterile filling space.

4. In response to the Appellant's argument regarding claim 18, the examiner maintains that the cover element (23) moves together with the separating element (21) for separation of the plastic tube as recited.

5. In response to the Appellant's argument regarding claims 19-21, the examiner maintains that the cover element moves synchronously with parts of the mold, and does not clear the filler opening until filling of the container (US 2004/0065983 - [0022], lines 1-8), and wherein the container is rinsed by or partly filled with the respective medium by means of the media delivery device (23), by way of the filler opening (as mention above, it is construed that heated air is the sterile medium).

6. In response to the Appellant's argument regarding claims 22-23, Hansen discloses the following:

> *"The sterile barrier is in the form of a heatable plate movable together with the separating element severing the tube, the plate being heated to a germ-killing temperature,* ***preferably above 150° C****."* ([0007]) (emphasis added),

thus Hansen clearly discloses the temperature of higher than 120° C, and a temperature with a range of 150° C to 200° C as recited.

7. In response to the Appellant's argument regarding claims 15, 16 and 26, the examiner maintains that it would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified Hansen et al. by incorporating the use of the sterile medium and vacuum device as taught by Zelina et al.

to provide means for sterilizing and decontamination the sterile filling space to achieve the condition as recited in claims 15, 16 and 26.

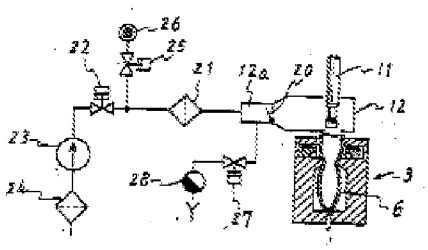
8. In response to the Appellant's argument (regarding claims 12 and 24) that:

> *"In contrast, claim 12 requires a method step wherein the sterile barrier covers the filler opening in the tube from its formation. Since the filling opening in the Japanese patent publication is not covered by the sterile barrier from the time of its formation to its filling, the subject matter of claim 12 or claim 24 is not anticipated or rendered obvious by the cited Japanese patent publication",*

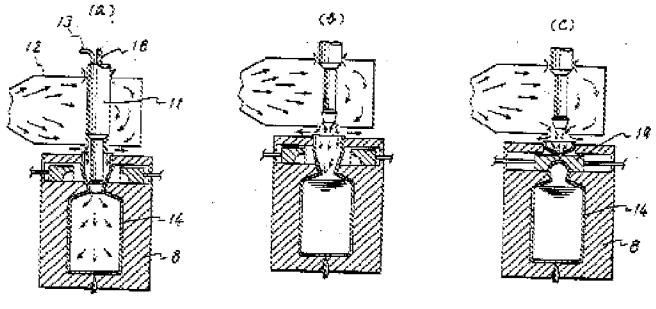
this is not found persuasive for the following reason:

It should be pointed out that the container (14) and its filler opening had yet to be formed as shown in Fig. 2 of Furui Koichi (JP 60049919 A), and in Fig. 3, the blowing and injection mandrel (11) accompanied by the sterile chamber (12) are moving down to cover the mold (8), and then the forming of the container (14) and its filler opening began. Therefore, it is construed that Furui Koichi (JP 60049919 A) clearly discloses "covering the filler opening by a sterile barrier at least from a formation time for the filler opening to filling of the tube" as recited – see the reproduction of Figs 2 and 3 below:

第 2 圖



第 3 圖



9. In response to the Appellant's argument regarding claims 13, 14, 17, 20 and 22-25, the examiner maintains that Furui Koichi (JP 60049919 A) discloses the claims as recited:

Regarding claims 13 and 14, wherein the sterile medium is air; and the sterile medium is conveyed at a specified pressure in the direction of the filler opening (Figs. 3a-c). Furui Koichi (JP 60049919 A) from the English translation provided by the Appellant, page 3, line 4 discloses: "Sterilized pressurized air", it is construed that qualified as "a specified pressure".

Regarding claims 17 and 25, the sterile barrier is configured as a plate-shaped cover element (it is construed that device 12 comprises plates that formed the device) which, after separation of the tube, covers the filler opening and provides it with a sterile medium until filling of the container is undertaken after its expansion below the sterile filling space (Fig. 3).

Regarding claim 20, the container (14) is flushed across the filler opening by the sterile medium by the media delivery device. Fig 3 clearly the flushing of sterilized medium across the filler opening from the sterilize chamber (12).

Regarding claims 22 an 23, it is construed that since Furui Koichi discloses that the medium is aseptic pressure air, it anticipated the temperature requirement (as recited in claim 22 and 23) so that the air is qualified as aseptic air. Furui Koichi (JP 60049919 A) from the English translation provided by the Appellant, page 5, lines 2-3 discloses: "reaches a temperature of at least 121° C, the temperature required for sterilization, and are thus sterilized" – it is construed that at least 121° C implied the

temperature range of 121º C and higher, therefore it suggests the temperature range as recited.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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